

CLAIMS

I claim:

1. A topical antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal, inclusive of human beings, in need thereof, said composition being substantially free of skin soothing agents, skin irritants, resins, phytic acid and salts thereof, chelating agents of a first and second compound as set forth below, siloxane polymers, sanguinarine, selenium sulfide, and substantially free of a thickening effective amount of an organic thickener, said composition comprising:
 - (a) water; and
 - (b) an antifungally active member selected from the group consisting of
 - (i) a first compound capable of generating in aqueous solution, at least one type of halogen ion X and H ion;
 - (ii) a second compound capable of generating in aqueous solution at least one halide ion X but not a significant amount of H ions in combination with a third compound capable of generating in aqueous solution H ions but not a significant amount of at least one halide ion X; and
 - (iii) mixtures thereof;

wherein each of said first and second compound comprises a transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr; and said at

least one halide ion X is selected from the group consisting of F, Cl, Br, I, halophosphates of each, and mixtures thereof;

(c) an alcohol selected from the group consisting of lower monohydric alcohols and lower dihydric alcohols, present in amounts of from 0% up to about 80% by volume based on

the final formulation;

(d) optionally a pH adjuster component selected from acids, bases and buffers in amounts sufficient to maintain the pH of said composition in the range of 2.0 to 4.0;

(e) said composition having a pH of about 2.0 to about 4.0,

wherein said composition is substantially free of said organic thickening agents in effective thickening amounts, substantially free of said skin soothing agents, substantially free of skin irritants, substantially free of resins, substantially free of phytic acid and salts thereof, substantially free of chelating agents for said first compound, if said first compound is present, substantially free of chelating agents for said second compound, if said second compound is present, substantially free of siloxane polymers, substantially free of sanguinarine, and substantially free of selenium sulfide

whereby when said composition is applied to said skin or nail, or to tissue surrounding or tissue underlying said nail, said fungal infection or symptoms associated therewith are effectively ameliorated.

2. The composition of claim 1 wherein said first compound is selected from halides of the formula



where Q is an alkali metal counter ion, M is said transition metal, X is said halide, A is an oxidation state of the metal atom M, and Y is an integer where at least one of an X ion and $M_{(>0 \text{ to } W)} X_{(1 \text{ to } WA+Y)}$ ion is a soluble species, or at least one of the oxides thereof or at least one of the hydrolysis products thereof is a soluble species, each of (WA+Y), Z, and P cannot exceed the coordination number for $(M^{A+})_W$, and W is a number of at least 1.

3. The composition of claim 1 wherein said first compound is present in an amount sufficient to saturate said composition.
4. The composition of claim 1 wherein said first compound is present in excess of its saturation in said composition.
5. The composition of claim 1 wherein said metal M is selected from the group consisting of zinc and tin.
6. The composition of claim 5 wherein said metal M is tin.
7. The composition of claim 1 wherein said halide is fluorine.

8. The composition of claim 2 wherein at least a portion of said compound is present as an oxide.
9. The composition of claim 2 wherein at least a portion of said compound is present as at least one hydrolysis product.
10. The composition of claim 2 wherein at least a portion of said compound is present as a mixed oxide/hydrolysis product.
11. The composition of claim 1 wherein said metal M is tin and said halide is fluoride.
12. The composition of claim 1 wherein said alcohol is selected from the group consisting of ethanol, isopropanol, propylene glycol, and mixtures thereof.
13. The composition of claim 1 wherein said alcohol is isopropanol.
14. The composition of claim 1 wherein component b is substantially the only antifungal component present in said composition.
15. The composition of claim 1 wherein component b is the only antifungal component present in said composition.

16. An antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal, inclusive of human beings, in need thereof, comprising

(a) water; and

(b) a weak hydrofluoric acid solution generator compound or hydrofluoric acid wherein the hydrofluoric acid concentration resulting in the solution is in sufficient to yield a pH in the range of not less than about 2.0, and not greater than about 4.0; whereby when said composition is applied to said skin or nail, or to tissue surrounding or tissue underlying said nail, said fungal infection or symptoms associated therewith are effectively ameliorated.

17. An antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal, inclusive of human beings, in need thereof, comprising

(a) water; and

(b) a metallic compound which is toxic to fungal organisms without being toxic to mammalian skin and nails, wherein said metallic compound is selected from the group consisting of

(i) a first compound capable of generating in aqueous solution, at least one type of halogen ion X and H ion;

(ii) a second compound capable of generating in aqueous solution at least one halide ion X but not a significant amount of H ions in combination with a third compound capable of generating in aqueous solution H ions but not a significant amount of at least one halide ion X; and

(iii) mixtures thereof;

wherein each of said first and second compound comprises a transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr; and said at least one halide ion X is selected from the group consisting of F, Cl, Br, I halophosphates of each, and mixtures thereof;

said compound being present in an amount sufficient to result in a pH of about 2.0 to about 4.0 or said composition further comprising a pH adjuster to bring said pH into the range of about 2.0 to about 4.0;

whereby when said composition is applied to said skin or nail, or to tissue surrounding or tissue underlying said nail, said fungal infection or symptoms associated therewith are effectively ameliorated.

18. An antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal, inclusive of human beings, in need thereof, comprising

(a) water; and

(b) a non-nail hardening but fungally toxic amount of a fluoride ion donor compound; said compound being present in an amount sufficient to result in a pH of about 2.0 to about 4.0 or said composition further comprising a pH adjuster to bring said composition into the pH range of about 2.0 to about 4.0;
whereby when said composition is applied to said skin or nail, or to tissue surrounding or tissue underlying said nail, said fungal infection or symptoms associated therewith are effectively ameliorated.

19. A non-nail hardening but antifungal composition for the treatment of a fungal infection of the skin or nails, or the symptoms associated therewith, in an animal, inclusive of human beings, in need thereof, comprising

(a) water; and
(b) a non-nail hardening but fungally toxic amount of a fluoride ion donor compound;
whereby when said composition is applied to said skin or nail, or to tissue surrounding or tissue underlying said nail, said fungal infection or symptoms associated therewith are effectively ameliorated without substantially hardening of said nail.

20. A method of treating a fungal infection of at least one of the skin and nails, comprising applying the composition of claim 1 to said fungal infection or to the skin or tissue surrounding said nails.

21. A method of making a composition of claim 1 comprising dissolving said compound into water in amounts sufficient to result in a pH in the range of about 2.0 to about 4.0 or in an effective concentration and, if necessary, adjusting the pH with a pH adjuster into the range of about 2.0 to about 4.0.
22. The method of making the composition of claim 21 wherein said metal is tin and said halide is fluoride, comprising converting said compound into an oxide thereof before dissolving said compound into said water.
23. The method of making the composition of claim 22 wherein said compound, before conversion into said oxide is stannous fluoride.
24. The method of claim 23 wherein at least a portion of said stannous fluoride is oxidized to stannic oxyfluoride prior to dissolving said compound into said water.
25. The method of claim 24 wherein said compound is dissolved into said composition up to said compound's saturation point.
26. The method of claim 25 wherein said composition has an excess of said compound present as solids together with said saturated solution of said compound.

27. A kit comprising a composition of claim 1 and labeling therefore including at least instructions on the use of said composition in a topical antifungal method.

28. A kit for making the composition of claim 1 comprising a solids component and a liquids component, said solids component comprising components b and optionally d of claim 1, said liquids component comprising components a and optionally c of claim 1, said kit further containing instructions for reconstitution thereof and use of the reconstituted composition as an antifungal topical composition.

29. A kit for making the composition of claim 1 comprising at least one solid component b of claim 1, at least one liquid component a of claim 1, optionally at least one solid component d of claim 1, and optionally one liquid component d of claim 1, and further comprising instructions for reconstituting said composition of claim 1 and use thereof as an antifungal topical composition.

30. A method of treating a dermatological condition comprising applying a composition comprising composition comprising:

- (a) water; and
- (b) an active member selected from the group consisting of
 - (i) a first compound capable of generating in aqueous solution, at least one type of halogen ion X and H ion;

- (ii) a second compound capable of generating in aqueous solution at least one halide ion X but not a significant amount of H ions in combination with a third compound capable of generating in aqueous solution H ions but not a significant amount of at least one halide ion X; and
- (iii) mixtures thereof;
wherein each of said first and second compound comprises a transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr; and said at least one halide ion X is selected from the group consisting of F, Cl, Br, I, halophosphates of each, and mixtures thereof;
- (iv) an alcohol selected from the group consisting of lower monohydric alcohols and lower dihydric alcohols, present in amounts of from 0% up to about 80% by volume based on the final formulation;
- (v) optionally a pH adjuster component selected from acids, bases and buffers in amounts sufficient to maintain the pH of said composition in the range of 2.0 to 4.0;
- (vi) said composition having a pH of about 2.0 to about 4.0.
wherein said condition is selected from the group consisting of acne, aphthous ulcers, bullous pemphigoid, candida, carbuncles, chiggers, folliculitis, furuncle, herpes simplex, herpes zoster, impetigo, lyme disease, molluscum contagiosum, pfiesteria, pimples, pityriasis rosea, psoriasis, ringworm, scabies, seborrheic dermatitis, seborrhea, tinea cruris, and tinea pedis.

31. The method of claim 30 wherein said condition is psoriasis.

32. The method of claim 30 wherein said first compound is selected from the group consisting of a tin halide and dilute hydrofluoric acid, and said second compound is a non-halide tin compound.

33. A method of treating a dermatological condition comprising applying a composition comprising:

(a) water; and

(b) an active member selected from the group consisting of

(i) a first compound capable of generating in aqueous solution, at least one type of halogen ion X and H ion;

(ii) a second compound capable of generating in aqueous solution at least one halide ion X but not a significant amount of H ions in combination with a third compound capable of generating in aqueous solution H ions but not a significant amount of at least one halide ion X; and

(iii) mixtures thereof;

wherein each of said first and second compound comprises a transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr; and said at

least one halide ion X is selected from the group consisting of F, Cl, Br, I, halophosphates of each, and mixtures thereof;

(c) an alcohol selected from the group consisting of lower monohydric alcohols, lower dihydric alcohols, and lower polyhydric alcohols, present in amounts of from 0% up to about 80% by volume based on the final formulation;

(d) optionally a pH adjuster component selected from acids, bases and buffers in amounts sufficient to maintain the pH of said composition in the range of 2.0 to 4.0;

(e) optionally a thickener selected from the group consisting of organic and inorganic thickening agents;

(f) optionally a surfactant selected from cationic, anionic, nonionic, amphoteric, and zwitterionic surfactants;

said composition having a pH of about 2.0 to about 4.0.

wherein said condition is selected from the group consisting of acne, aphthous ulcers, bullous pemphigoid, candida, carbuncles, chiggers, folliculitis, furuncle, herpes simplex, herpes zoster, impetigo, lyme disease, molluscum contagiosum, pfiesteria, pimples, pityriasis rosea, psoriasis, ringworm, scabies, seborrheic dermatitis, seborrhea, tinea cruris, and tinea pedis.

34. A method of treating a dermatological condition comprising applying a composition comprising an active member selected from the group consisting of

(i) a first compound capable of generating in aqueous solution, at least one type of halogen ion X and H ion;

(ii) a second compound capable of generating in aqueous solution at least one halide ion X but not a significant amount of H ions in combination with a third compound capable of generating in aqueous solution H ions but not a significant amount of at least one halide ion X; and

(iii) mixtures thereof;

wherein each of said first and second compound comprises a transition metal selected from the group consisting of Ag, Cu, Fe, Ga, Ge, In, Ni, Sn, Ti, Zn, and Zr; and said at least one halide ion X is selected from the group consisting of F, Cl, Br, I, halophosphates of each, and mixtures thereof;

wherein said condition is selected from the group consisting of acne, aphthous ulcers, bullous pemphigoid, candida, carbuncles, chiggers, folliculitis, furuncle, herpes simplex, herpes zoster, impetigo, lyme disease, molluscum contagiosum, pfiesteria, pimples, pityriasis rosea, psoriasis, ringworm, scabies, seborrheic dermatitis, seborrhea, tinea cruris, and tinea pedis.

35. The method of claim 34 wherein said composition is in the form of a solution, a suspension, a gel, a lotion, a cream, or an ointment.

36. The method of claim 34 wherein said composition is contained in an impregnated bandage, a topical or transdermal or transcutaneous patch.

37. The method of claim 34 wherein said composition is aqueous.